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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,132	07/20/2004	Gerhard Schmaus	3968-120	1516
30448 7590 03/10/2008 AKERMAN SENTERFITT P.O. BOX 3188 WEST PALM BEACH, FL 33402-3188				
EXAMINER				
CHONG, YONG SOO				
ART UNIT		PAPER NUMBER		
1617				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/502,132

Applicant(s)

SCHMAUS ET AL.

Examiner

YONG S. CHONG

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/3/2007 has been entered.

Claim(s) 6 has been cancelled. Claim(s) 1-5, 7-21 are pending. Claim(s) 1-2, 4, 7-8, 10-11 have been amended. Claim(s) 1-5, 7-21 are examined herein.

Applicant's arguments have been fully considered but found not persuasive. The rejection(s) of the last Office Action are maintained for reasons of record and modified below as a result of the new claim amendments. The following new rejection will also apply.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7, 9-21 are rejected under 35 U.S.C. 103(a) as being obvious over Clarkson et al. (US Patent Application 2001/0036964 A1) in view of Eggensperger et al. (US Patent 5,670,160), Riebel et al. (US Patent Application 2003/0100613 A1), and Cupferman et al. (US Patent Application 2002/0098211 A1).

The instant claims are directed to a synergistic anti-microbial composition comprising two or more 1,2-alkanediols and a preservative.

Clarkson et al. teach an anti-microbial composition comprising an iron (III) chelator, water, and polyhydric alcohol (abstract). The iron (III) chelators are utilized as anti-microbial agents in the composition (section 0001). Preferred polyhydric alcohols include 1,2-pentanediol, 1,2-hexanediol, and 1,2-octanediol, or mixtures thereof (section 0065) with amounts ranging from 1 to 20% by weight (section 0062). Additional anti-microbial agents (section 0077) as well as other additives (section 0087), such as preservatives (section 0088) may be added to the composition.

Generally, mere optimization of ranges will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "When the general conditions of a claim are

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disclosed in the prior art, it is not inventive to discover the optimal or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also *In re Peterson*, 315 F. 3d at 1330, 65 USPQ 2d at 1382 "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." MPEP 2114.04.

However, Clarkson et al. fail to disclose expressly a composition comprising the particular combination of alkyldiols herein or the specific preservatives such as 1,2-dibromo-2,4-dicyanobutane, 2-phenoxyethanol, and 3-iodo-2-propinyl-butyl carbamate.

Eggensperger et al. teach that 1,2-dibromo-2,4-dicyanobutane (col. 16, lines 15-20) and 2-phenoxyethanol (col. 15, lines 27-35) can be used as preservatives or biocides.

Riebel et al. teach that 3-iodo-2-propinyl-butyl carbamate can be used as a fungicide (section 0328).

Cupferman et al. disclose a novel antimicrobial composition comprising at least one polyol in combination with 2-hydroxy-4-(1-methylethyl)cyclohepta-2,4,6-trien-1-one or sodium capryl lactyl lactylate (section 0002). The polyol is disclosed to be 1,2-alkanediols (section 0005), specifically comprising 4 to 8 carbon atoms (section 0012), such as 1,2-octanediol or 1,2-pentanediol (section 0013). Furthermore, such compositions are disclosed to possess synergistic antimicrobial action (section 0008).

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed invention was made to make a synergistic composition

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comprising the alkyldiols herein, according to Clarkson et al. and to include 1,2-dibromo-2,4-dicyanobutane and 2-phenoxyethanol taught by Eggensperger et al. and 3-iodo-2-propinyl-butyl carbamate taught by Riebel et al. in the anti-microbial composition taught by Clarkson et al.

A person of ordinary skill in the art would have been motivated to make a synergistic composition comprising the 1,2-alkanediols herein because: (1) Clarkson et al. discloses 1,2-alkanediols for use in antimicrobial compositions and (2) Cupferman et al. discloses synergistic antimicrobial action in compositions comprising 1,2-alkanediols. Therefore, one of ordinary skill would have had a reasonable expectation of success in formulating a synergistic antimicrobial composition, as disclosed by Cupferman et al., comprising 1,2-alkanediols of different chain lengths for preserving a cosmetic or food product from microbes, bacteria, and fungi.

Examiner respectfully points out that the intended use is given no patentable weight in a composition.

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish from each other. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Thus, the intended use of a composition claim will be given no patentable weight.

It is further respectfully pointed out that a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). See MPEP 2111.02.

It is also noted that the limitations regarding Kull values are inherent because a composition and its properties are inseparable. "Products of identical chemical composition can not have mutual exclusive properties." Any properties exhibited by or benefits from are not given any patentable weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the disclosed properties are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product.

Claim 8 is rejected under 35 U.S.C. 103(a) as being obvious over Greff (FR 2 747 572, partial translation).

The instant claims are directed to a composition consisting of two or more straight chain 1,2-alkanediols, wherein the chain length is different and in the range of 5 to 10 C atoms.

Greff teach that cosmetic dermatopharmaceutical and veterinary composition consisting of at least one antimicrobial alkane-diol of formula I, where R is a linear chain having 5 to 12 carbon atoms (claim 1). Preferred alkane-diols are octane-1,2-diol (example 1 and claim 2) and hexane-1,2-diol (example 2). The concentration of the alkane-diols varies from 0.1 to 10% (p/p) (claim 4).

However, Greff fail to disclose a specific combination of two alkane-diols with a linear chain between 5 to 10 carbon atoms.

It would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to have formulated a specific combination of two alkane-diols with a linear chain between 5 to 10 carbon atoms as taught by Greff.

A person of ordinary skill in the art would have been motivated to formulate a specific combination of two alkane-diols with a linear chain between 5 to 10 carbon atoms because: (1) Greff discloses alkane-diols of formula I, where R is a linear chain having 5 to 12 carbon atoms, in general, as having antimicrobial properties; and (2) Greff discloses the preferred antimicrobials, octane-1,2-diol and hexane-1,2-diol. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in formulating a cosmetic dermatopharmaceutical and veterinary composition consisting of the antimicrobials, octane-1,2-diol and hexane-1,2-diol.

Response to Arguments

Applicant argues that the cited prior art references, particularly Cupferman et al., do not teach synergistic antimicrobial action between different straight chain 1,2-alkanediols with chain length in the range of 5 to 10 carbon atoms. Applicant also supports this conclusion by submitting Kull values to quantify the synergism (Tables 3 and 7 of Applicant's specification). Accordingly, a showing of unexpected results should overcome the prima facie case of obviousness.

As pointed out by the Applicant that Cupferman et al. showing of synergism appears to result from the combination between a polyol and a specific antimicrobial, and not from a combination of two or more polyols. However, Applicant's showing of unexpected results does not overcome the obviousness rejection because the results in the specification are not commensurate with the scope of the instant claims. It is noted that the instant claims do not recite any limitation on the amounts of the 1,2-alkanediols. Applicant's specification only show data for the following amounts: 0.25%, 0.5%, 1%, 2%, and 3 % for the disclosed 1,2-alkanediols. This is not enough to support the entire range of up to 100% as claimed.

Furthermore, the limitation in claims 4, 7, 8, 10-11 regarding Kull values being 1.0 or less is confusing considering Applicant's showing of synergism. How can there be a showing of synergism if the claims are drawn to Kull values of 1.0, when synergism only arises in cases where the Kull value is less than 1.0? Applicant is reminded that Kull values of 1.0 are attributed to purely additive effects and not synergism.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong S Chong/
Examiner, Art Unit 1617

YSC